



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA-2013-N-0002]

Withdrawal of Approval of New Animal Drug Applications; Roxarsone

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal approval of five new animal drug applications (NADAs) for roxarsone oral dosage form products at the sponsor's request because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: John Bartkowiak, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9079, john.bartkowiak@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007 has requested that FDA withdraw approval of the following five NADAs for roxarsone oral dosage form products, used to make medicated drinking water for chickens, turkeys, and swine, because the products are no longer manufactured or marketed:

NADA	Proprietary Name
005-414	REN-O-SAL (roxarsone) Tablets
006-019	Zuco Poultry Tablets
006-081	Korum Improved Formula
008-274	Pig Scour Tablets
093-025	3-NITRO (roxarsone) Soluble

Elsewhere in this issue of the Federal Register, FDA gave notice that approval of NADAs 005-414, 006-019, 006-081, 008-274, and 093-025, and all supplements and amendments thereto, is withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these voluntary withdrawals of approval.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§§ 520.2087, 520.2088, and 520.2089 [Removed]

2. Remove §§ 520.2087, 520.2088, and 520.2089.

Dated: December 20, 2013.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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